

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

LYNN OXENBERG and RONALD LEWIS

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity
as Secretary of the United States Department
of Health and Human Services,

Defendant.

Civil Action No. 20-738-CMR

ORDER

AND NOW, this _____ day of _____, 202____, upon
consideration of the defendant's Rule 12(b)(1) Motion for to Dismiss and any response thereto, it
is ORDERED that the defendant's motion is GRANTED. The plaintiff's complaint is
DISMISSED WITH PREJUDICE.

BY THE COURT:

HONORABLE CYNTHIA M. RUGE
Judge, United States District Court

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THE DEFENDANT'S RULE 12(B)(1) MOTION TO DISMISS

Pursuant to Fed. R. Civ. P. 12(b)(1), the defendant, the Secretary of the U.S. Department of Health and Human Services, hereby moves this Court to dismiss for lack of subject-matter jurisdiction the complaint of the plaintiffs Lynn Oxenberg and Ronald Lewis. Plaintiffs here lack Article III standing to bring this action because they have suffered no injury-in-fact that could be redressed by a favorable ruling.

WHEREFORE, for the reasons stated in the accompanying Memorandum of Law, the defendant respectfully requests that this Court grant his Motion and dismiss the plaintiffs' complaint with prejudice.

Respectfully submitted,

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Dated: November 13, 2020

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**THE DEFENDANT'S MEMORANDUM OF LAW
IN SUPPORT OF RULE 12(B)(1) MOTION TO DISMISS**

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I. **INTRODUCTION**

The Court is familiar with this case, as summary judgment has been fully briefed since May 19, 2020. The plaintiffs, Lynn Oxenberg and Ronald Lewis, filed a pre-answer motion for summary judgment seeking judicial review of the denial of Medicare claims for each plaintiff for certain months of tumor treatment field therapy (“TTFT”) with Novocure’s Optune device to treat glioblastoma multiforme (“GBM”), a form of brain cancer. The pending cross-motions for summary judgment address whether the defendant, the Secretary of the U.S. Department of Health and Human Services (the “Secretary”), is collaterally estopped because of certain administrative law judge (“ALJ”) decisions. The plaintiffs recently filed a motion to introduce evidence from another TTFT/Optune case into the summary judgment record in this case. The Secretary opposes that request in a separate brief. Dkt. No. 31. However, despite having the same national counsel in other cases as in the instant case, the plaintiffs fail to mention the most important recent development: three other district courts have dismissed essentially identical TTFT/Optune cases for lack of subject-matter jurisdiction. *See Pehoviack v. Azar*, 2020 WL 4810961 (C.D. Cal. July 22, 2020); *Komatsu v. Azar*, 2020 WL 5814116 (C.D. Cal. Sept. 24, 2020); *Prosser v. Azar*, 2020 WL 6266040 (E.D. Wis. Oct. 21, 2020). The legal conclusions reached by those other district courts on common issues likewise warrant dismissal of this case.

As in those other cases, the plaintiffs here lack Article III standing to bring this action because they have suffered no injury-in-fact that could be redressed by a favorable ruling. The ALJ decisions denying Medicare coverage for the plaintiffs’ TTFT claims found that the plaintiffs were not financially responsible for paying for their treatment. Accordingly, no matter the outcome of this case, the plaintiffs have suffered no legal injury because they will not be required to pay any money out of pocket for TTFT. Consistent with these three recent decisions,

the Secretary moves to dismiss this case for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1).

II. FACTUAL AND LEGAL BACKGROUND

The Secretary refers the Court to its Cross-Motion for Summary Judgment for a fuller discussion of the statutory, regulatory, and factual background in this case. *See* Dkt. No. 17 at 4-9. The Secretary emphasizes and amplifies the background relevant to this motion.

A. Advance Beneficiary Notices

This case involves issues arising from denial of Medicare claims. If Medicare coverage is denied, the circumstances dictate whether Medicare, the supplier, or the beneficiary bears responsibility. Medicare will pay a denied claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). If a supplier expects Medicare to deny payment, it can shift the risk of non-coverage to the beneficiary by providing her with advance written notice (called an “Advance Beneficiary Notice” or “ABN”) detailing the specific reason why the item probably will not be covered. 42 C.F.R. § 411.404(b). The ABN helps the beneficiary decide whether to accept responsibility to pay out-of-pocket for the item that Medicare may not cover. In the absence of a valid ABN, a supplier cannot bill the beneficiary if Medicare coverage is denied.

See 42 U.S.C. § 1395pp; *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 997-98 (9th Cir. 2012) (explaining that a valid ABN is required “for the supplier to shift liability to the beneficiary”); *Cal. Clinical Lab. Ass'n v. Sec. of HHS*, 104 F. Supp. 3d 66, 72-72 (D.D.C. 2015) (same).¹

¹ *See also* Medicare Claims Processing Manual Chapter 30 – Financial Liability Protections, §§ 50.2.1 (If notice of liability is not given, “providers may not shift financial

B. Facts Regarding Plaintiffs' Lack of Financial Responsibility for TTFT

On May 30, 2019, an ALJ denied Plaintiff Lewis's claim for TTFT from July – October 2018. AR at 833-840. The ALJ noted that Novocure had “appropriately challenged the reasonableness of the [applicable Local Coverage Determination for TTFT (the “LCD”)] through the . . . separate reconsideration appeal, however, concerns that an LCD is not supported by the medical community or medical research are not a basis for an ALJ to decline application of a relevant LCD.” AR at 838. Under the Medicare regulations, the ALJ was not authorized to “set aside or review the validity of [an LCD] for purposes of a claim appeal.” AR at 838 (quoting 42 C.F.R. § 405.1062(c)). The ALJ also concluded that this plaintiff failed to meet the criteria for coverage under the proposed 2019 LCD. AR at 838-39. Nevertheless, the ALJ held that Plaintiff Lewis was not financially responsible for the cost of the Optune device:

The file did not contain an Advance Beneficiary Notice or any other form of notice. The Beneficiary neither knew, nor reasonably should have been expected to know, that any of the services would not be covered by Medicare. The liability of the Beneficiary is waived.

However, the Provider, is presumed to have known the requirements for submitted claims. 42 C.F.R. § 411.406(e). The record contains no evidence to rebut the presumption that the Provider knew, or should have known, the services were not covered under the Medicare program. Therefore, the Provider is liable for the non-covered charges pursuant to § 1879.

AR at 839.

On September 5, 2019, an ALJ denied Plaintiff Oxenberg's claim for TTFT from April – June 2018. AR at 103-10. The ALJ “decline[d] to exceed their authority by reviewing the

liability to beneficiaries . . . if Medicare denies the claim”), 50.2.2 (a supplier “who fails to comply with the ABN instructions risks financial liability and/or sanctions.”), 50.4.1 (deeming suppliers to be “notifiers,” which must issue ABNs), 50.4.2 (“Notifiers are required to give an ABN to a [] Medicare beneficiary . . . before providing him/her with a Medicare covered item or service that may not be covered”), available at: <http://www.cms.gov/manuals/downloads/clm104c30.pdf>.

validity of or categorically rejecting the LCD at issue.” AR at 108-109 (citing 42 C.F.R. § 405.1062). The ALJ also concluded that the record “lacks the evidence to overcome the substantial deference owed to the LCD.” AR at 108. The ALJ, however, held that Plaintiff Oxenberg had no personal responsibility for her claim denial:

Under § 1879 of the Act, the Medicare program makes payment for non-covered services when neither the beneficiary nor the supplier knew, or could reasonably have been expected to know, that the items or services would be found non-covered on the grounds that they were not medically reasonable and necessary. A provider must give the beneficiary written notice that Medicare will not pay, before the services are provided. MCPM, Pub. 100-04, Ch. 30, § 30.1. The record does not include an Advance Beneficiary Notice (ABN) or any other indication that the Beneficiary knew or could have been reasonably expected to know that the items in question would be excluded from coverage. The supplier received CMS notices and is responsible for knowing [the] Medicare regulation. 42 C.F.R. §41 1.406(e). The supplier is responsible for knowing that the disputed services were not medically reasonable and necessary. Thus, the supplier remains responsible for the non-covered charges.

AR at 109.²

The plaintiffs have fully exhausted their administrative remedies, because the ALJ decisions denying their claims became final when the Council did not timely respond to their notices of escalation. AR at 1-2, 726-27. The plaintiffs filed the instant action under 42 U.S.C § 405(g) instead of awaiting a hearing before the Medicare Appeals Council. *Id.*

On March 30, 2020, the plaintiffs filed a pre-answer motion for summary judgment. Dkt. No. 12. In that motion, at 13-14, the plaintiffs addressed ABNs, which had been discussed with the Court at previous status conferences. The plaintiffs did not dispute the Secretary’s contention that they were not financially responsible for the TTFT/Optune claims at issue.

On April 20, 2020, the Secretary answered the plaintiffs’ Complaint (Dkt. No. 16), filed the administrative record (*see* Dkt. No. 18), and opposed the plaintiffs’ motion and cross-moved

² Section 1879 of the Social Security Act is incorporated at 42 U.S.C. § 1395pp.

for summary judgment (Dkt. No. 17). Subsequent briefing on the cross-motions for summary judgment followed and was completed by May 19, 2020. *See* Dkt. 29.

III. RULE 12(B)(1) MOTION TO DISMISS STANDARD

A motion to dismiss for lack of standing arises under Federal Rule of Civil Procedure 12(b)(1) because “standing is a jurisdictional matter.” *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007). The lack of subject-matter jurisdiction defense is never waived. Fed. R. Civ. P. 12(h)(1). “If the court determines at *any time* that it *lacks subject-matter jurisdiction*, the court *must dismiss the action.*” Fed. R. Civ. P. 12(h)(3) (emphasis added).

At issue in a Rule 12(b)(1) motion to dismiss for lack of subject-matter jurisdiction is the trial court’s ““very power to hear the case.”” *Norman v. United States*, 1996 WL 377136, at *1 (E.D. Pa. July 3, 1996) (quoting *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884 (3d Cir. 1977)). Plaintiff has the burden to prove that jurisdiction does in fact exist and ““the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case.”” *Norman*, 1996 WL 377136, at *1 (citing *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1408-09 (3d Cir. 1991), *cert. denied*, 501 U.S. 1222 (1991)). The court is “not confined to the allegations in the Complaint . . . and can look beyond the pleadings to decide factual matters relating to jurisdiction.” *Cestonaro v. United States*, 211 F.3d 749, 752 (3d Cir. 2000).

IV. ARGUMENT

The U.S. Constitution limits federal-court jurisdiction to actual cases or controversies. *Raines v. Byrd*, 521 U.S. 811, 818 (1997); U.S. Const. Art. III, § 1. Standing to sue is a doctrine derived from this limitation on judicial power. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). The “irreducible constitutional minimum” of standing consists of three elements: the plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the

challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision. *Id.* (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). The plaintiffs bear the burden of establishing these elements. *Id.* Just as in the three other recent district court decisions involving other TTFT beneficiaries using Novocure’s Optune device (*Pehoviack, Komatsu, and Prosser*), the plaintiffs do not—and cannot—show that the elements of standing are present, especially not an injury in fact.

A. The Plaintiffs Have Not Suffered an Injury in Fact

1. The plaintiffs have not alleged a past injury in fact.

To establish injury in fact, the plaintiffs must show that they suffered “an invasion of a legally protected interest” that is “concrete and particularized” and “actual or imminent, not conjectural or hypothetical.” *Spokeo*, 136 S.Ct. at 1548 (quoting *Lujan*, 504 U.S. at 560). A “concrete” injury must be “real” and “not abstract.” *Id.*

Although injuries may be either tangible or intangible, neither type of injury exists here. *Id.* at 1549. Plaintiffs have not alleged a tangible injury, because the Secretary cannot hold them financially responsible for the cost of the Optune device. The ALJ decisions on appeal held that Plaintiffs’ liability has been waived under section 1879 of the Social Security Act. AR at 109, 839. Accordingly, the Supreme Court’s decision in *Thole* is dispositive as to the plaintiffs’ lack of standing. *Thole v. U.S. Bank N.A.*, 140 S.Ct. 1615 (2020). In *Thole*, the Court found that the plaintiffs had no concrete stake in the lawsuit where “the outcome of this suit would not affect their future benefit payments.” 140 S.Ct. 1615, 1619 (2020). The Court explained that if the plaintiffs “were to *lose* this lawsuit, they would still receive the exact same monthly benefits that they are already slated to receive, not a penny less. If [the plaintiffs] were to *win* this lawsuit, they would still receive the exact same monthly benefits that they are already slated to receive,

not a penny more.” *Id.* (emphasis in original). Here, if the plaintiffs prevail, the Secretary will not pay them a penny; rather, the Secretary would pay the supplier of the Optune device, Novocure. If the plaintiffs lose, they will not owe the Secretary a penny. Because the plaintiffs have no concrete stake in this lawsuit, they lack Article III standing.

The plaintiffs might argue that they have a statutory right to appeal the denial of their Medicare claims. But that intangible right does not create Article III standing. The *Spokeo* Court explained:

Congress’ role in identifying and elevating intangible harms does not mean that a plaintiff automatically satisfies the injury-in-fact requirement whenever a statute grants a person a statutory right and purports to authorize that person to sue to vindicate that right. Article III standing requires a concrete injury even in the context of a statutory violation. For that reason, [plaintiff] could not, for example, allege a bare procedural violation, divorced from any concrete harm, and satisfy the injury-in-fact requirement of Article III.

Id. at 1549; *see also Kamal v. J. Crew Group*, 918 F.3d 102, 110-12 (3d Cir. 2019) (applying *Spokeo*). The relevant statute here is 42 U.S.C. § 405(g), which authorizes a beneficiary to appeal a final decision of the Secretary to federal court. *Rutherford v. Barnhart*, 399 F.3d 546, 552 (3d Cir. 2005). The plaintiffs have exercised their right to file under section 405(g), and there is no allegation that the Secretary interfered with their ability to file this lawsuit. Accordingly, there is no statutory violation, much less a concrete injury.

Absent any concrete injury, the plaintiffs may argue that they have a “substantive” right that Medicare, rather than Novocure, bear the expense of their claims. However, two elements must be present for a statutory violation to constitute a cognizable injury: (1) Congress must have determined that the statutory violation is a sufficient injury to satisfy Article III; and (2) the harm must have “long been seen as injurious” under the common law. *See Spokeo*, 136

S.Ct. at 1549; *Kamal*, 918 F.3d at 111-15.³ Neither element is present here.

First, there is no statutory entitlement to Medicare coverage for all claims, much less any law stating that a beneficiary has been injured absent any financial responsibility for her claim. To the contrary, coverage for durable medical equipment, such as the Optune device, cannot be made *unless* the device is “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” 42 U.S.C. § 1395y(a)(1)(A). Medicare has broad authority to determine whether it covers particular medical services, and beneficiaries must submit claims in order to obtain coverage. If a claim is denied, the beneficiary must exhaust administrative remedies before proceeding to federal court. The Secretary has discretion to approve or reject claims, and the law merely affords beneficiaries the *procedural right* to challenge a claim denial. No statute guaranteed that the plaintiffs’ claim would be covered, and no statute identifies what injury a beneficiary paying nothing out-of-pocket has suffered. Here, the plaintiffs merely allege that their claim appeals were wrongfully decided, which is a procedural violation “divorced from any concrete harm” that cannot “satisfy the injury-in-fact requirement of Article III.” *Spokeo* at 1549; *see also Thole*, 140 S.Ct. at 1619-20.

Second, the Third Circuit has rejected the proposition that plaintiffs have standing to sue an insurer, like Medicare, despite their claims being fully paid by a third-party, such as Novocure. In *Wheeler v. Travelers Ins. Co.*, the plaintiff incurred medical expenses in connection with an automobile accident, all of which were fully paid between Medicare and

³ In *Spokeo*, the Court provided examples of the type of procedural violations that can be sufficient to constitute injury in fact, such as the inability to obtain public information used for voting, or failure to obtain information subject to disclosure under federal law. 136 S.Ct. at 1549.

Travelers. 22 F.3d 534, 536 (3d Cir. 1994). Nevertheless, plaintiff sued Travelers for the portion of expenses paid by Medicare. *Id.* The Third Circuit held that plaintiff did not have Article III standing, because “[s]he has not alleged or established that she suffered any actual or threatened injury from Travelers’ denial of her claim for no-fault benefits for she acknowledges that Medicare paid the medical expenses for which she seeks a recovery.” *Id.* at 538. The plaintiff’s allegation that “Travelers wronged, but did not injure her” was insufficient for standing. *Id.*; see, e.g., *Hull v. Burwell*, 66 F. Supp. 3d 278, 282 (D. Conn. 2014) (citing *Wheeler* and finding that a plaintiff had no standing to sue Medicare where the Medicaid program had assumed all of plaintiff’s liability); *Estate of Lake v. Secretary of HHS*, 1989 WL 200974, at *2 (D.N.H. Oct. 27, 1989) (finding that a plaintiff lacked standing to sue for Medicare reimbursements where she had no out-of-pocket loss).

Citing *Wheeler* as controlling law, the Third Circuit subsequently held that a party had no standing where that party “no longer has anything personally to gain from a favorable outcome” because the party had been fully indemnified and signed over its right to any recovery. *Koops v. XL Ins. Am., Inc.*, 620 F. App’x 110, 112-13 (3d Cir. 2015). Likewise, the plaintiffs have no out-of-pocket liability and nothing to gain from arguing that Medicare, rather than Novocure, should be financially responsible for paying her claim.

In *California Clinical*, a provider and beneficiary filed a challenge under the Medicare Act to an LCD, and the Secretary moved to dismiss for lack of standing. *Cal. Clinical Lab. Ass’n v. Sec. of HHS*, 104 F. Supp. 3d 66, 69 (D.D.C. 2015). The court found that the beneficiary failed to allege an injury because “she was not charged personally.” *Id.* at 79. In addition, the statutorily conferred right to file an LCD challenge was insufficient for standing, because it was procedural and merely a “means to achieve the ultimate end the recipients seek.”

Id. at 76-78. The right to file did not confer a “substantive right or entitlement.” *Id.* at 78. The plaintiffs could not allege a deprivation of their statutory right to file given that the Secretary had not prevented them from filing their action. *Id.* Likewise, section 405(g) merely afforded the plaintiffs the procedural right to file this action, and, having exercised that right, the plaintiffs cannot allege any statutory violation or injury in fact.

2. The plaintiffs have not alleged an “impending” future injury that could give rise to standing.

Although the plaintiffs may argue that they have interest in estopping the Secretary from denying future claims, that purported interest cannot create standing. First, the plaintiffs may not rely on speculative or hypothetical future harms to establish standing. *Lujan*, 504 U.S. at 564 & n.2; *see also Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (“injury must be certainly impending to constitute injury in fact . . . allegations of possible future injury are not sufficient.”) (citing *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)). The mere possibility that the plaintiffs’ claims *might* be denied in the future, and that the plaintiffs *might* be financially responsible for those claims, cannot create standing. Indeed, the plaintiffs assert that their other TTFT claims have been approved and do not allege that they would have been financially responsible for those claims if they had been denied.⁴ *See* Compl. ¶¶ 22, 28.

Second, collateral estoppel generally will not apply when “controlling facts or legal principles have changed significantly since the [prior] judgment.” *Karns v. Shanahan*, 879 F.3d 504, 514 (3d Cir. 2018) (alteration in original) (quoting *Montana v. United States*, 440 U.S. 147, 155 (1979)). Here, there was a significant change between the 2014 LCD, which categorically

⁴ The plaintiffs have not disputed that Novocure has not billed the plaintiffs for the treatment at-issue (which was rendered over two years ago), and, as noted above, has not met the requirements to validly bill them. *See* Plaintiffs’ MSJ (Dkt No. 12) at 13-14. Speculation that Novocure might bill the plaintiffs in the future cannot create standing.

denied coverage for TTFT, and the 2019 LCD, which allowed coverage of TTFT under certain circumstances. Because collateral estoppel could not apply after September 1, 2019, the plaintiffs' future claims are not at issue. Meanwhile, the only unfavorable decisions dated before September 1, 2019 are those on appeal, in which the plaintiffs have no concrete interest.

In *California Clinical*, the court found that a beneficiary's assertions of future injury were speculative given that her future claims may be covered by Medicare, and there was no allegation that she had or will receive an ABN that would make her "financially responsible for . . . claims denied in the future." 104 F. Supp. 3d at 80. Likewise, the plaintiffs have not shown a substantial probability that they will be financially responsible for their TTFT in the future.

C. The Plaintiffs Cannot Satisfy the Other Elements of Standing

The plaintiffs cannot satisfy the second element of standing. Because the Secretary does not hold the plaintiffs financially responsible for the claims at issue, any alleged injury that the plaintiffs may suffer would not be fairly traceable to the Secretary. In particular, Novocure has complete discretion as to whether to bill the plaintiffs for their treatment, and any independent action that Novocure takes is not traceable to the Secretary. *See Lujan*, 504 U.S. at 560 (an injury cannot be the "result of independent action of some third party not before the court."). Nor could any action that Novocure takes as the result of the outcome of this lawsuit affect the plaintiffs' standing. *See McNair v. Synapse Group Inc.*, 672 F.3d 213, 226 (3d Cir. 2012) ("[S]tanding is determined at the outset of the litigation.") (citing *Davis v. FEC*, 554 U.S. 724, 734 (2008)).

The plaintiffs have also not met the third element of standing, because any alleged injury would not be redressed by a favorable ruling. Even if the plaintiffs prevailed, Novocure would still have discretion to change its billing practices in the future. A lawsuit against the Secretary

should not proceed due to a hypothetical billing dispute between the plaintiffs and Novocure.

D. Three District Courts Have Dismissed for Lack of Standing in Identical TTFT/Optune Cases

Courts have dismissed for lack of Article III standing in identical cases litigated by the plaintiffs' national counsel involving Medicare claims denials for TTFT/Optune.⁵ In *Pehoviack*, the court found that a plaintiff who was not required to pay for her treatment and alleged possible future injuries lacked standing:

Plaintiff was not required to pay for her treatment. Nor does [p]laintiff allege that she has been otherwise injured by the [Council] Decision. Plaintiff argues in her Opposition that she may be held personally liable for future treatments, or that her TTFT supplier might require her to sign an agreement assuming liability for the costs of future Medicare denials. None of these potential injuries, however, has come to pass; indeed, [p]laintiff has received favorable Medicare decisions for treatment periods subsequent to the denial at issue here.

2020 WL 4810961, at *3 (C.D. Cal. July 22, 2020) (citation omitted). The court noted that although it was "sympathetic to [p]laintiff's apprehension over the denial of benefits . . . especially considering the severity of her illness and the reported outcomes of TTFT treatment," plaintiff had not "directly experienced any injury stemming from the [d]enial, and the potential consequences she discusses in her Opposition remain speculative." *Id.*

Likewise, the *Komatsu* court found that a plaintiff who bore no financial responsibility for her TTFT claim lacked standing. 2020 WL 5814116, at *2 (C.D. Cal. Sept. 24, 2020) ("This action must be dismissed as [plaintiff] lacks Article III standing. [Plaintiff] has suffered no

⁵ In another TTFT case litigated by the plaintiffs' counsel, a Magistrate Judge in the Middle District of Pennsylvania issued a Report and Recommendation that, *inter alia*, denied the Secretary's motion to dismiss. *Piekanski v. Azar*, 20-cv-687 (M.D. Pa.) [Dkt. No. 63 (Oct. 6, 2020) at 25-28]. The decision does not address any of the three district court cases on point; although, *Komatsu* issued after the motion to dismiss was fully briefed and *Prosser* post-dates the Report. The Secretary filed objections to the Report, and plaintiff did not defend the grounds given in the Report for denying the Secretary's motion to dismiss. *See id.* Dkt. Nos. 64 at 5-16, 68 at 2.

injury. Even though [plaintiff's] requests for coverage were denied and her appeals were rejected, her provider bears the financial burden for paying for those services, not her.”). The court rejected the argument that a future claim denial could confer standing, writing that plaintiff “does not cite any binding law to demonstrate that such a denial of benefits alone confers standing.” *Id.* The court noted that “while [plaintiff] could be liable for future treatments, she has not demonstrated that the threatened injury, the possibility of her being financially responsible for TTFT, is ‘certainly impending.’ Absent such a showing, her injury is merely hypothetical or conjectural, and therefore, one that the Court lacks power to redress.” *Id.* (quoting *Clapper*, 568 U.S. at 409).

Finally, the court in *Prosser* dismissed for lack of Article III standing because “[i]t is undisputed that Novocure, the supplier of [p]laintiff's TTFT device—not [p]laintiff herself—is ‘financially liable’ and ‘responsible’ for the costs of the TTFT treatment.” 2020 WL 6266040, at *1 (E.D. Wis. Oct. 21, 2020). The court also found that plaintiff's speculation concerning future injuries did not suffice for standing. *Id.* at *1 (“Although [p]laintiff argues . . . that she may be held personally liable for future treatments, or that her TTFT supplier might require her to sign an agreement assuming liability for the costs of future Medicare denials, these potential injuries have not come to pass and are too speculative to establish standing.”). The *Pehoviack*, *Komatsu*, and *Prosser* decisions considered identical facts and arguments regarding TTFT/Optune treatments and dismissed those cases for lack of subject-matter jurisdiction. The same result should follow here.

V. CONCLUSION

For the foregoing reasons, and because the plaintiffs' lack of standing cannot be rectified by amending their Complaint, the Secretary respectfully requests that the Court grant his motion to dismiss for lack of subject-matter jurisdiction and dismiss the Complaint with prejudice.

Respectfully submitted,

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Dated: November 13, 2020

CERTIFICATE OF SERVICE

I hereby certify that on this day, I caused a true and correct copy of the foregoing motion to dismiss to be served on all counsel of record via the Court's CM/ECF system.

/s/ Matthew E. K. Howatt
MATTHEW E. K. HOWATT
Assistant United States Attorney

Dated: November 13, 2020